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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,052	03/01/2000	John Harada	023070-077630US	3907

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	13

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/516,052	HARADA ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2000 and 21 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *1-8, 10-20, 23-27, 30-34, 37-38, 40-41, 44-45, 50-53, 56-57, 59-62 and 64-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse in Paper No. 12 is acknowledged. Applicant elects with traverse the claims of Group II (claims 4-5, 23-24, 50-51 and 59-60) if claims 1, 21, 47 and 58 are included in Group II. If claims 1, 21, 47 and 58 are not included in Group II, Applicant elects with traverse Group I (claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 46-49, 54-55, 58, 63 and 69).

2. The traversal is on the ground(s) that the examination of claims 1-69 would not create an undue burden for the examiner, that a search of the sequences recited in independent claims 1, 21, 47 and 58 will identify art relevant to the claims of Group II because this genus encompasses all the polynucleotides encoding the particular sequences recited in the dependent claims, that the sequences exemplified in the specification are not different sequences with different functions or structures but are related sequences in that they recite a common structural motif and have a common functional role in plants, and that Group VI which is directed to antisense constructs can be searched with sense constructs and therefore should be combined with the remaining restriction groups.

3. This is not found persuasive because the sequences exemplified in the specification, although they may be related sequences in reciting a common structural motif and having a common functional role in plants, are patentably distinct sequences because they are derived from separate genes, or because they are derived from functionally distinct regions of a gene (i.e. the promoter or the coding region). According to the specification, SEQ ID NOS:1 and 2 correspond to the coding region of the *Arabidopsis* LEC1 gene, SEQ ID NOS: 19 and 20

correspond to the coding region of the *Arabidopsis* LEC1-Like gene, SEQ ID NOS: 21 and 22 correspond to the coding region of the *Phaseolus coccineus* LEC1-Like gene, and nucleotides 1 to 1998 of SEQ ID NO: 3 and SEQ ID NOS:23 and 24 correspond to promoter regions of the *Arabidopsis* LEC1 gene. When claims are directed to the SEQ ID NOS of patentably distinct sequences, a separate search is required for each sequence. Resource allocations at the PTO are currently such that no more than one patentably distinct sequence may be searched in a single application. Accordingly, claims 1, 21, 47 and 58 are not included in Group II, and Group I (claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 46-49, 54-55, 58, 63 and 69) is examined in the instant application. This is also not found persuasive because a search of Group VI requires a different classification search than the remaining restriction groups.

4. Claims 4-8, 10-20, 23-27, 30-34, 37-38, 40-41, 44-45, 50-53, 56-57, 59-62 and 64-68 are withdrawn from consideration as being directed to nonelected inventions.

5. The requirement is still deemed proper and is therefore made FINAL.

Priority

6. A foreign priority is not claimed.

Information Disclosure Statement

7. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 4, is attached to the instant Office action.

Drawings

8. The drawing itself is not labeled as Figure 1.

Claim Objections

9. Claims 35 and 42 are objected to for depending from claims directed to nonelected inventions

10. Claim 54 is objected to because of the following informalities: the word "embryonic" is misspelled. Appropriate correction is required.

11. Claim 55 is objected to because of the following informalities: the claim does not end with a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 21, 22, 28, 29 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

14. The claims are drawn to isolated nucleic acids encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2, with the proviso that the nucleic acid is not clone MNJ7.

15. However, the specification does not set forth what specific structural or physical features are required in the claimed isolated nucleic acids. The specification only discloses the sequence of the *Arabidopsis* LEC1 gene (SEQ ID NO:1), the *Arabidopsis* LEC1-Like gene(SEQ ID NO:19) which was initially identified in the Arabidopsis BAC clone MNJ7 by a BLAST search of an Arabidopsis database (page 40 line 28 to page 40 line2), and the *Phaseolus coccineus* LEC1-Like gene (SEQ ID NO:21). Except for SEQ ID NO:1, the specification does not disclose isolated nucleic acids encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2 with the proviso that the nucleic acid is not clone MNJ7. The specification does not disclose whether any of these isolated nucleic acids other than SEQ ID NO:1 encodes a functional protein. The structural and physical features of the claimed isolated nucleic acids cannot be ascertained in the absence of information about their functional activities. The identities of the claimed isolated nucleic acids are uncertain.

16. See also *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

> "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA … Accordingly, the specification does not provide a written description of the invention …"

17. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed isolated nucleic acids, and given the high

level of unpredictability in this art of defining isolated nucleic acid sequences that would have LEC1 function, one skilled in the art would not have been in possession of the claimed isolated nucleic acids at the time this application was filed.

18. Claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a LEC 1 polypeptide comprising SEQ ID NO:2, does not reasonably provide enablement for an isolated nucleic acid encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

19. The claims are drawn to isolated nucleic acids encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2, and to expression cassettes, transgenic cells and plants comprising said isolated nucleic acids. The claims are also drawn to methods of introducing said isolated nucleic acids into a cell.

20. The specification only discloses the sequence of the *Arabidopsis* LEC1 gene (SEQ ID NO:1) which encodes a polypeptide (SEQ ID NO:2) having 55-63% identity with the B domains of other CBF polypeptides (Example 1 pages 31-38). The specification also discloses that ectopic expression of SEQ ID NO:1 in transgenic lec1-1 mutant plants induces embryonic characteristics and the expression of genes that are specifically active in embryos (Example 2 pages 38-40). In addition, the specification discloses the sequence of the *Arabidopsis* LEC1-Like gene(SEQ ID NO:19) which encodes a polypeptide of SEQ ID NO:20, and that ectopic expression of SEQ ID

NO:19 in transgenic lec1-1 mutant plants complements the lec1-1 mutation (Example 4 pages 40-42). The specification discloses the sequence of the *Phaseolus coccineus* LEC1-Like gene (SEQ ID NO:21) which encodes a polypeptide of SEQ ID NO: 2 (Example 5 pages 42-43).

21. The specification does not disclose isolated nucleic acids encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2, or the effect of introducing these nucleic acids into a plant.

22. Guidance for making and using the claimed invention is necessary for enablement because the homology of predicted amino acid sequences to known proteins does not always predict the function of the homologous sequences (Doerks et al. 1998, Trends in Genetics, Vol. 14, No. 6, pages 248-250). Doerks et al. teach that incorrect or incomplete sequence information within a database affects the predictive capacity of the database (Page 248 column 1 paragraph 1). Doerks et al. also teach that query searches may identify shared homology with multiple groups of functionally unrelated proteins (Page 248 column 3 second full paragraph), that regions of shared homology may be nonfunctional regions (Page 248 column 3 third full paragraph), and that the degree of shared homology within a functional region does not always predict a conservation of the functional mechanism of that region (Page 248 column 3 fourth full paragraph). Because the functions of nucleic acid sequences that are less than 85.5% identical to SEQ ID NO:4 or that encode polypeptides less than 83.7% identical to SEQ ID NO:5 have not been demonstrated, the claimed invention is not enabled by the specification in the absence of further guidance or example.

23. Given the unpredictability of determining the function of nucleic acid sequences on the basis of predicted amino acid sequence homology alone, the absence of guidance in the

specification for making and using isolated nucleic acids encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2, the lack of working examples, and given the breadth of the claims which encompass any isolated nucleic acid encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2, as well as methods involving said nucleic acid sequences, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

24. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25. Claims 21, 47, 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

26. Claim 21 is indefinite in the recitation of the vernacular term "clone MNJ7". Because many different clones could be designated "clone MNJ7", the claim is indefinite.

27. Claims 47, 54 and 55 are indefinite in reciting "modulating" and "modulated". It is unclear what type of transcriptional modulation occurs when these methods are practiced.

Claim Rejections - 35 USC § 102

28. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

29. Claims 21, 22, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by either of Lotan et al. (GenEmbl Accession AF036684, 02 July 1998) or Feng et al. (GenBank Accession AQ251011, 07 October 1998).

30. The claims are drawn to an isolated nucleic acid encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2, wherein the B domain comprises a polypeptide sequence with an amino terminus at amino acids 28-35 and a carboxy terminus art amino acids 103-117 with the proviso that the nucleic acid is not clone MNJ7.

31. Each of Lotan et al. and Feng et al. teaches an isolated nucleic acid encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2, wherein the B domain comprises a polypeptide sequence with an amino terminus at amino acids 28-35 and a carboxy terminus art amino acids 103-117 with the proviso that the nucleic acid is not clone MNJ7.

32. Accordingly, claims 21, 22, 28 and 29 are anticipated by either of Lotan et al. or Feng et al.

33. Claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Lotan et al. (Cell, Vol. 93, pages 1195-1205, June 26, 1998).

34. The claims are drawn to isolated nucleic acids encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2, and to expression cassettes, transgenic cells and plants comprising said isolated nucleic acids. The claims are also drawn to methods of introducing said isolated nucleic acids into a cell.

35. Lotan et al. teach an isolated nucleic acid encoding a LEC 1 polypeptide comprising a subsequence at least 68% identical to the B domain of SEQ ID NO:2, and an expression cassette, transgenic cells and plants comprising said isolated nucleic acid, as well as methods of introducing said isolated nucleic acids into a cell. (page 1198 Figure 4, page 1200 Figure 6, page 1201 column 1 first full paragraph, page 1203 column 2 second full paragraph).

36. Accordingly, claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69 are anticipated by Lotan et al.

Double Patenting

37. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

38. Claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,235,975 (May 22, 2001). Although the conflicting claims are not identical, they are not patentably distinct from each other because the isolated LEC1 nucleic acids of the instant invention encompass the LEC1 nucleic acids in claims 1-34 of U.S. Patent No. 6,235,975.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
November 30, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600